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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,837	12/04/2003	Manne Satyanarayana Reddy	BULK 3.0-033	8513

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EXAMINER	
COPPINS, JANET L	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,837	REDDY ET AL	
	Examiner	Art Unit	
	Janet L. Coppins	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) *17-32 and 35-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,6-12 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-56 are pending in the instant application.

Information Disclosure Statement

2. Applicant's Information Disclosure Statement (IDS), submitted July 19, 2004, has been considered by the Examiner. Please refer to the signed copy of Applicant's PTO-1449 form, attached herewith.

Response to Amendment

3. Receipt is acknowledged of Applicants' Response to the Restriction Requirement, filed August 14, 2006, which has been reviewed by the Examiner and entered of record in the file.

Applicant's election **with traverse** of Group I, claims 1-16, 33, and 34, drawn to amorphous ziprasidone hydrochloride, its pharmaceutical compositions, and a method of use, is acknowledged. Applicants argue that the restriction requirement does not comply with established policy and is improper, since Examiner Sackey has allegedly, "not determined that the various groups of claims can support separate patents," since, "... the pending claims relate only to the single known chemical compound having the adopted name "ziprasidone," and to the hydrochloride salt of the compound," such that, "... all of the pending claims can be examined together without any undue burden."

The Examiner respectfully disagrees. Regarding the traversal, Groups I-VI of Examiner Sackey's Restriction Requirement represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

4. Invention I is related to Inventions II, II, and IV, as product made and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as

claimed can be used to make other and materially different product or (2) that the product can be made by another materially different process (MPEP 806.05(f)). In the instant case, the product as claimed can be made by another materially different process as demonstrated in the claims, since Applicants recite several different processes of preparation.

5. Inventions II-IV and VI are distinct and independent from Inventions I and V because they are directed to different statutory classes of invention and the practice of one of Inventions II-IV or VI would not result in the practice of the other Invention, i.e. treating a psychosis is not a process that prepares *per se* the compounds of the instant invention.

6. Regarding Inventions I-IV and V-VI, if Applicants are alleging that there is no patentable difference between the polymorphic forms of ziprasidone and the amorphous form, then by Applicants' own admission, the hydrate forms of in U.S. Pat. 5,312,925 would be applicable art against Applicants' amorphous forms recited in Group I.

7. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VI, restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made FINAL.

8. Accordingly, claims 17-32 and 35-56 are withdrawn from consideration as being drawn to non-elected inventions.

9. Applicant is reminded that upon the cancellation of subject matter to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2 and 6-12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 2 is rejected for incorporating a figure by reference. Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993), see MPEP 2173.05(s). The Examiner recommends incorporating the actual figure itself into the claims, or using the following language, "The compound of claim 1, having the X-ray diffraction pattern with characteristic peaks expressed in d-values (A) at ..."

(b) Regarding claims 2 and 10, the term "substantially" renders the claims indefinite because it is unclear as to what limitations define the claimed invention. It is unclear what Applicants are intending to encompass within the compound/composition since the boundaries of the claims are not discernable, see MPEP § 2173.05(d).

(c) Claims 6-9, 11, and 12 are rejected for reciting, "...at least," which is indefinite, since the Specification lacks a standard for measuring the degree intended, i.e. there is no upper limit defined in the claims. Applicants have created ambiguity in their recited compositions

since they have only set limitations that define the minimum amount, therefore the claims are inclusive of any composition that contains more than the recited minimum amount. See MPEP 2173.05(b)-(c).

(d) Claims 10- 12 are confusing for reciting "...crystalline Form I" yet it is unclear which crystalline form Applicants are referring to. Polymorphism is defined as the existence of different solid forms (modifications) of a compound which have the same chemical composition but different structures. Different polymorphic forms of ziprasidone HCl are known in the art, and by merely reciting the term "Form I," Applicants have not provided a clear definition as to what crystalline form is intended to be claimed, and therefore the limitations of the claim cannot be ascertained.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 16 rejected under 35 U.S.C. 112, first paragraph, as not being fully enabled. While various psychotic or intellectual impairment diseases/disorders that may be treated by administering ziprasidone are listed on page 1 of the specification, the number of diseases and conditions encompassed by claim 16 is not enabled. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, the claims are directed to many diseases and conditions that are not enabled in the specification, including encompassed by the language of claim 16.

The nature of the invention

The nature of the invention is of methods of treating many different diseases or conditions that are encompassed by the terminology "a psychosis," comprising administering the instant claimed compound to a patient in need thereof.

The state of the prior art

It is well recognized in the medical art that ziprasidone is useful in the treatment of psychotic disorders of the schizophrenic types, and for treating symptoms such as anxiety, agitation, excessive aggression, tension and social or emotional withdrawal in psychotic patients.

The predictability or lack thereof in the art

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. Also, such as psychotic patients require administering antipsychotics, on the other hand, treating depression employs the use of anti-depressants such as SSRIs.

The amount of direction or guidance present

The specification has not enabled any methods of using the instant claimed compounds. The only mention of treating any disorders or diseases at all is found on page 11, where Applicants state in paragraph 52 that the instant claimed compounds are useful for treating "a

psychosis." Furthermore, treatment of the claimed distinct diseases are normally disease or symptom oriented, thus are highly individualized, i.e. treating the symptoms of attention disorders such as ADHD (inattention, hyperactivity, and impulsivity) would not employ the same methods as treating schizophrenia. The efficacy of an individual compound against a specific disease or symptom needs to be specifically and individually supported by factual evidence. Such evidence has not been described or supported by the specification.

The presence or absence of working examples

The data provided in the disclosure is insufficient evidence for methods of treating all psychotic disorders or "psychoses" as instantly claimed. In fact, Applicants have provided no disclosure whatsoever in the Specification, they have only described the known crystalline form of ziprasidone and its utility, and by their own admission, "It is known that polymorphic forms of the same drug may have substantial differences in certain pharmaceutically important properties." Therefore, one skilled in the art would not assume that the amorphous form of ziprasidone hydrochloride would exhibit the same properties and have the same efficacy for treating psychotic disorders. The standard of 35 USC 112, first paragraph rejections is that the application *itself* must inform, rather than direct, others to find out for themselves, please see *In re Garnder*, 166 USPQ 138.

The breadth of the claims and the quantity of experimentation needed

Applicants are claiming a method of treating a broad number of diseases or conditions, as recited in claim 16. The argument that the diseases claimed by the Applicants are all treated by administering the known drug ziprasidone is insufficient support that the claimed compounds have specific efficacy in current available form for treating all psychotic disorders/psychoses.

One of ordinary skill in the art without direction, would be unable to treat each and every disease/condition encompassed by claim 16, using the instant claimed compounds. One of skill in the art would need to determine what listed diseases would be benefited by ziprasidone and would furthermore then have to determine whether the claimed amorphous ziprasidone HCL compounds would provide treatment of all of the diseases and conditions by said activity.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of claim 1 for the treatment of all disorders encompassed by the language of claim 16. As a result, necessitating one of skill to perform an exhaustive search for which claimed diseases can be treated by the amorphous ziprasidone HCl compound in order to practice the claimed invention. The Examiner recommends incorporation specific diseases/disorders that amorphous ziprasidone HCl is enabled for treating.

Conclusion

14. Claims 1-56 are pending in the application. Claims 2, 6-12, and 16 are currently rejected, and claims 17-32 and 35-56 are currently withdrawn.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
December 10, 2006

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